Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparing the effect of Dimethyl fumarate and Placebo on infarct size and NIHSS score in acute ischemic stroke patients

Protocol summary

Study aim
1. Comparing the effect of dimethyl fumarate and Placebo on NIHSS score of patients, before and after the trial 2.Comparing the effect of dimethyl fumarate and Placebo on infarct size of patients, before and after the trial 3.finding a suitable drug for reducing disabilities among stroke patients

Design
The study is two arm parallel group, double blinded, randomized clinical trial

Settings and conduct
Patients who are admitted the Shariati hospital will be assigned to the trial according to the inclusion and exclusion criteria. Then they undergo a clinical examination and an MRI scan will be carried out for them at the beginning of the trial. Then they will be divided into Placebo or Drug groups according to the randomization table. There will be 16 patients in each group. Another examination and MRI will be carried out 15 to 45 days after the first dose of drug/placebo. The patients and the doctor are both blind to the drug/placebo groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients at the age of 18-85 years old; Patients with acute neurological symptoms that have been diagnosed as ischemic stroke patient by a neurologist. Non inclusion criteria: Patients with prior sensitivity to dimethyl fumarate; Patients with serious infections; Pregnancy and lactation; Immunologic deficiencies in the past 6 months; Patients receiving rtPA; Patients who undergo endovascular treatment.

Intervention groups
Intervention group: the group receiving 240mg Dimethyl fumarate, three times a day for one week. Control group: the group receiving Placebo, three times a day for one week

Main outcome variables
Infarct size; National Institute of Health Stroke Scale(NIHSS)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180224038841N1**
Registration date: **2019-01-13, 1397/10/23**
Registration timing: **registered_while_recruiting**

Last update: **2019-01-13, 1397/10/23**
Update count: **0**

Registration date
2019-01-13, 1397/10/23

Registrant information

Name
Seyed Mehrdad Savar

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 8822 0040

Email address
sm-savar@student.tums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-12-31, 1397/10/10

Expected recruitment end date
2019-04-09, 1398/01/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Comparing the effect of Dimethyl fumarate and Placebo on infarct size and NIHSS score in acute ischemic stroke patients

Public title
Evaluation of efficacy of Dimethyl Fumarate in stroke
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients at the age of 18-85 years old Patients with acute neurological symptoms who have been diagnosed as ischemic stroke by a neurologist
Exclusion criteria:
Patients with prior sensitivity to dimethyl fumarate Patients with serious infections Pregnancy and lactation Immunologic deficiencies in the past 6 months (i.e. cancer,lymphoma, HIV and viral hepatitis) Patients receiving rtPA Patients who undergo endovascular treatment Liver function test more than 2 times of normal range Initial WBC count under 3500 lymphopenia under 500
Age
From **18 years** old to **85 years** old
Gender
Both

Phase
2
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **32**
Randomization (investigator's opinion)
Randomized
Randomization description
According to the table of random numbers patients are assigned to drug or placebo group.
Blinding (investigator's opinion)
Double blinded
Blinding description
It's a double blind clinical trial. The care provider, the outcome assessor, the patients and the investigator are all blind. The drugs are labeled by "A" and "B" and the process of labeling the drugs (dimethyl fumarate and placebo) with "A" and "B" is done by a clinical pharmacist who is not involved in any other process in the trial.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tehran University of Medical Sciences
Street address
Central Headquarters of Tehran University of Medical Sciences, Keshavarz Blvd. and Ghodss St. Intersection
City
Tehran
Province
Tehran
Postal code
1417653761
Approval date
2018-02-21, 1396/12/02
Ethics committee reference number
IR.TUMS.PSRC.REC.1396.4572

Health conditions studied

1

Description of health condition studied
Ischemic Stroke
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Infarct Size in Magnetic Resonance Imaging(MRI)
Timepoint
An MRI at the beginning of the trial and a second one after 15 to 45 days from starting Dimethyl fumarate or Placebo
Method of measurement
using automatic softwares

2

Description
National Institute of Health Stroke Scale (NIHSS)
Timepoint
at the beginning of the trial and 30 days after starting Dimethyl fumarate
Method of measurement
NIHSS checklist

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Dimethyl fumarate 240mg , three times a day for one week
Category
Treatment - Drugs

2

Description
Control group: Placebo , three times a day for one week
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Shariati Hospital
Full name of responsible person
Dr. Siamak Abdi
Street address
Shariati Educational Research Center, Jalal Al Ahmad three way, North Kargar street
City
Tehran
Province
Tehran
Postal code
1411713135
Phone
+98 21 8490 1000
Fax
+98 21 8863 3039
Email
shariatihosp@tums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr. Mohammadali Sahraeian
Street address
Central Headquarters of Tehran University of Medical Sciences, at the corner of Qods street, Keshavarz bulevard and Qods street intersection
City
Tehran
Province
Tehran
Postal code
1417653761
Phone
+98 21 8163 3686
Email
rcco@tums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Seyed Mehrdad Savar
Position
Student
Latest degree
A Level or less
Other areas of specialty/work
Medical Pharmacy
Street address
Neurology ward, first floor, Shariati Hospital, Jalal Al Ahmad three way, North Kargar street
City
Tehran
Province
Tehran
Postal code
1411713135
Phone
+98 21 8822 0040
Fax
Email
mehrdad.savar@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Seyed Mehrdad Savar
Position
Student
Latest degree
A Level or less
Other areas of specialty/work
Medical Pharmacy

Street address
Neurology ward, first floor, Shariati Hospital, Jalal Al Ahmad three way, North Kargar street
City
Tehran
Province
Tehran
Postal code
1411713135
Phone
+98 21 8822 0040
Fax
Email
mehrdad.savar@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Seyed Mehrdad Savar
Position
Student
Latest degree
A Level or less
Other areas of specialty/work
Medical Pharmacy
Street address
Neurology ward, first floor, Shariati Hospital, Jalal Al Ahmad three way, North Kargar street
City
Tehran
Province
Tehran
Postal code
1411713135
Phone
+98 21 8822 0040
Fax
Email
mehrdad.savar@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
only the data related to the main and secondary objectives of the study can be shared.
When the data will become available and for how long
Starting access 3 months after publication
To whom data/document is available
only available for people working at academic institutions and universities
Under which criteria data/document could be used
the request must be sent to the corresponding author by email and it will be decided per case.
From where data/document is obtainable
By sending the request for the corresponding author through an email.
What processes are involved for a request to access data/document
The reason of asking for the data along with the request for the data must be sent to the corresponding author via email.After evaluating the reason for asking the data, the data will be provided if possible.
Comments